

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/2010 has been entered.

Status

Applicant's amendment to the claims filed 2/24/2010 are acknowledged. With entry of the amendment, claims 16-19 are pending and subject to restriction as follows.

Election/Restrictions

As amended on 2/24/2010, claims 16-19 are directed to a plurality of patentably distinct species of the claimed methods for providing a modified CpG-containing phosphorothioate oligonucleotide and for reducing the side effects of a CpG-containing phosphorothioate oligonucleotide. The species recited in each of claims 16-19 are distinguished one from the other by the particular type of gene or RNA transcript complementary to the oligonucleotide used in the method, wherein the target gene or RNA transcript may be from:

1. endogenous mammalian chromosomal DNA
2. a eukaryotic pathogen
3. a prokaryotic pathogen, or

4. any virus selected from HIV-1 or -2, influenza virus, herpes simplex type 1 or 2 virus, Epstein-Barr virus, cytomegalovirus, respiratory syncytial virus, hepatitis B virus, or hepatitis C virus.

Applicant is required to elect, endogenous mammalian chromosomal DNA, eukaryotic pathogen, prokaryotic pathogen, or a single virus from those recited in the claims (see #4, above). It is noted that the viruses listed in #4 are reasonably considered to be eukaryotic pathogens. Thus, should applicant elect eukaryotic pathogen (#2), applicant is further requested to elect a single virus (#4) from those recited in the claims. Similarly, election of a single virus would be considered election of a eukaryotic pathogen.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. For example, the structural characteristics (e.g., the nucleotide sequence) of an oligonucleotide complementary to an RNA transcript encoded by a eukaryotic viral gene would more likely than not be distinct from one that is complementary to an RNA encoded by an endogenous mammalian gene. Accordingly, the methods of providing and modifying said oligonucleotides would have materially different designs and produce different relative effects. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. At present, no claim is generic to each of the claimed species.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g.,

Art Unit: 1635

searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Art Unit: 1635

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
March 31, 2010